

Safety Alert Aug.2025

Abrocitinib- Risk of Neutropenia

EDA performs label update to include the following:

4 CLINICAL PARTICULARS 4.8 Undesirable effects

System organ class	Uncommon
Blood and lymphatic system disorders	Neutropenia

Background:

Neutropenia

Neutropenia is a medical condition characterized by an abnormally low number of neutrophils, a specific type of white blood cell, in the bloodstream. Neutrophils are a critical component of the immune system and are the body's primary defense against bacterial and fungal infections. When the neutrophil count is low, a person is at a significantly higher risk of developing serious infections.

Therapeutic Indication

Abrocitinib is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

Reference

MHRA (click Here)